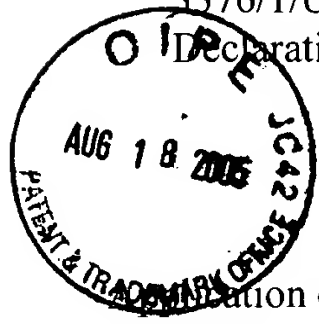


Serial No. 09/941,206

3376/1/US (26648)

Declaration (Perez)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor of: Fedde et al.
Serial No.: 09/941,206
Filed: 28 Aug 2001
Title: USE OF AN ALDOSTERONE RECEPTOR ANTAGONIST TO IMPROVE
COGNITIVE FUNCTION
Group Art Unit: 1617
Examiner: Jennifer M. Kim
Confirmation No.: 5686
Docket No.: 3376/1/US

DECLARATION OF ALFONSO T. PEREZ, M.D. UNDER 37 CFR §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Alfonso T. Perez, M.D., declare and state as follows:

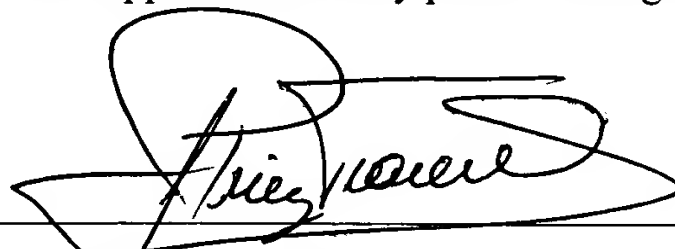
- 1) I am currently employed as Vice President, Clinical Research at Takeda Global Research and Development, Inc. ("Takeda"). Previously, I was employed by G.D. Searle & Co. ("Searle") from 1985 until 2000, most recently serving as Senior Medical Director – Cardiovascular Franchise. During my employment at Searle I was actively involved in the clinical study of aldosterone receptor antagonists, particularly the aldosterone receptor antagonist eplerenone.
- 2) I have reviewed and am familiar with U.S. Patent Application Serial No. 10/440,691 which is entitled "Triple Therapy of Angiotensin Converting Enzyme Inhibitor Epoxy-Steroidal Aldosterone Antagonist and Diuretic or Digoxin for Treatment of Cardiovascular Disease" and claims priority from March 5, 1999 (the "Alexander Application").
- 3) I also have reviewed and am familiar with U.S. Patent No. 6,592,902 which is entitled "Controlled Release Eplerenone Compositions" and claims priority from December 9, 1998 (the "Thosar Application").
- 4) The "Biological Evaluation II" section contained at page 35 through page 45 of the Alexander Application, publication number US 2004/0077611 A1 dated April 22, 2004,

describes a clinical study protocol for evaluating the use of eplerenone to treat cardiovascular disease in eligible patients. The described protocol also includes a provision for assessing Quality of Life of the patients at screening, at week 4, at month 3, at month 6, at month 12, and at the final visit of the study.

- 5) I believe that I am the first and sole inventor of the use of eplerenone to improve Quality of Life in patients suffering from or susceptible to cardiovascular disease. I conceived of this invention prior to December 9, 1998 (the priority date of the Thosar Application). In fact, I conceived of including a Quality of Life Assessment in the clinical study protocol described in the Biological Evaluation II section of the Alexander Application, and contributed the specific language contained in the Biological Evaluation II section that relates to the Quality of Life assessment.
- 6) Although Kenton Fedde and Joseph Tooley are listed as co-inventors in the pending application, they contributed subject matter other than the use of eplerenone to improve Quality of Life in patients suffering from or susceptible to cardiovascular disease.
- 7) I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such willful false statements may jeopardize that validity of the application or any patent issuing therefrom.

8/17/2005

Date



Alfonso T. Perez, M.D.